

F&P File #243609-06/rag

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
JOHNNY WILLIAMSON,

Plaintiff,

-against-

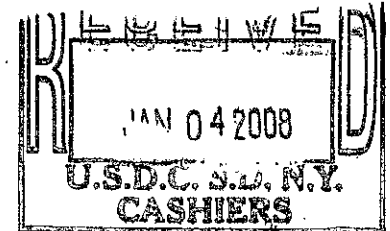
FOREST LABORATORIES, INC. and
FOREST PHARMACEUTICALS, INC.,

Defendants.
-----X

08 CV 00717

COMPLAINT

Plaintiff Demands
Trial by Jury



Plaintiff, by attorneys, FINKELSTEIN & PARTNERS, LLP, as and for the Verified

Complaint herein alleges upon information and belief the following:

STATEMENT OF THE CASE

1. This is an action to recover damages for personal injuries sustained by Plaintiff, JOHNNY WILLIAMSON, as the direct and proximate result of Defendant's wrongful conduct of the Defendants, FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC., in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Lexapro.

JURISDICTION AND VENUE

2. Jurisdiction exists as against Defendants, FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC., pursuant to:

(a) 28 U.S.C. Section 1332, in that Plaintiff, JOHNNY WILLIAMSON, is a citizen and resident of the State of Georgia, the Defendant, FOREST LABORATORIES, INC., is

incorporated in the State of Delaware and maintains its principal place of business in the State of New York, Defendant, FOREST PHARMACEUTICALS, INC., is incorporated in business in the State of Delaware and maintains its principal place of business in the State of Missouri, and the amount in controversy exceeds the sum of \$75,000.00 exclusive of interest and costs.

(b) 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and Defendants, FOREST LABORATORIES, INC. and FOREST PHARMACEUTICALS, INC., are subject to personal jurisdiction in the Judicial District of the Southern District of New York and may be deemed to reside in the Southern District of New York.

PARTIES

3. That at all times hereinafter mentioned, Plaintiff, JOHNNY WILLIAMSON, was and still is a resident of the County of Glynn, State of Georgia.

4. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., was and still is a foreign corporation organized under the laws of the State of Delaware.

5. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., was and still is a foreign corporation authorized to do business in the State of New York.

6. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., was and still is a business entity actually doing business in the State of New York.

7. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., was and still is a foreign corporation organized under the laws of the State of Delaware.

8. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., was and still is a foreign corporation authorized to do business in the State of New York.

9. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., was and still is a business entity actually doing business in the State of New York.

10. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Lexapro, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

11. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Lexapro, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

12. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., committed a tortious act inside the State of New York, which caused injury to Plaintiff inside the State of Georgia.

13. That at all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., committed a tortious act outside the State of New York, which caused injury to Plaintiff inside the State of Georgia.

14. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

15. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

16. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., committed a tortious act inside the State of New York, which caused injury to Plaintiff inside the State of Georgia.

17. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., committed a tortious act outside the State of New York, which caused injury to Plaintiff inside the State of Georgia.

18. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

19. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., expects or should reasonably expect its acts to have

consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

20. At all times relevant hereto, Defendants, FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC., manufactured, produced and marketed Lexapro, also known as escitalopram oxalate, one of the drugs in the family of selective serotonin reuptake inhibitors ("SSRIs").

21. In the last decade there has been a host of peer-reviewed scientific literature linking the SSRI drugs, of which Lexapro is one, to violence – both self-directed and directed towards others.

FACTS

22. Plaintiff, JOHNNY WILLIAMSON, was born on April 1, 1974.

23. In approximately December 2005, Plaintiff was diagnosed with depression.

24. Prior to 2005, Plaintiff began to experience symptoms of depression because of his wife leaving him.

25. In December 2005, Plaintiff was given a sample packet of approximately 10 mg of Lexapro by his family physician.

26. Plaintiff's physician prescribed Lexapro because he believed that Lexapro was effective in treating depression in adults, an opinion based upon research that had been distributed by Defendants. However, this medication did not help the condition for which it was prescribed and was not FDA approved for such condition.

27. Lexapro is an orally administrated psychotropic drug that Defendants have marketed as if it was a single, highly selective medicine which has the ability to treat a host of maladies.

28. Defendants do not know exactly how or why Lexapro elevates the mood of some individuals. Defendants just believe that the drug works well to a "statistically significant" degree in a population of depressed adult patients.

29. Since the early 1980s, Defendants have been aware of serious and life threatening side effects to individuals who take Lexapro, especially children and adolescents who take Lexapro.

30. Initially, Lexapro seemed to help with Plaintiff's mood, nervousness, anxiety, and mental condition.

31. Within a few weeks after taking Lexapro, however, Plaintiff's condition started to deteriorate.

32. Plaintiff started to feel increased anxiety, agitation, hostility, and sadness. There were periods where Plaintiff began to feel severe bouts of suicidal ideation. Plaintiff continued to take his prescribed dosage of Lexapro.

33. On January 9, 2006, Plaintiff unsuccessfully attempted to commit suicide, thereby sustaining serious injury.

34. Defendants have been aware for many years that persons who are prescribed Lexapro are much more likely to commit self-directed violence and even attempt suicide.

35. Even though Defendants were aware of this information, they intentionally withheld this information from various governmental agencies and the public at large all the while knowing that physicians were prescribing Lexapro to children throughout the world.

36. On August 2002, Defendants reported that "Lexapro, the single-isomer of Celexa, is reported to be well-tolerated and may offer some distinct advantages over the drug it is derived from." Furthermore, Defendants stated that Lexapro was "well-tolerated and had a drop out rate

comparable to placebo at the 10 mg dosage . . . the most common adverse events (number given in parentheses are Lexapro vs. placebo) were: nausea (15% vs. 7%), insomnia (9% vs. 4%), ejaculation disorder (9% vs. <1%), somnolence (6% vs. 2%), sweating increased (5% vs. 2%) and fatigue (5% vs. 2%)." There is no mention concerning the increased risks of agitation, hostility, and suicidal ideation.

37. Prior to when Plaintiff was first prescribed Lexapro in December 2005, Defendants marketed Lexapro as if it was a highly selective medicine which had the ability to treat a host of maladies with one simple pill. For example, in addition to the original indicated use as an antidepressant for adults, Lexapro was promoted and eventually approved for generalized anxiety disorder in adults and for off-label uses in adolescents.

38. Prior to April 2005, Defendants were aware that some adolescents who were prescribed Lexapro and other SSRIs for depression or anxiety were much more likely to commit self-directed violence and were at an increased risk of suicidal behavior.

39. Dr. J. John Mann, an expert retained by another SSRI manufacturer, coauthored a paper in which he discusses the phenomenon of iatrogenic suicide and postulates that there may well be a "small vulnerable subpopulation" of patients for whom SSRIs pose a paradoxical risk of suicide or aggression.

40. In a 1991 paper titled "The emergence of suicidal ideation and behavior during antidepressant pharmacotherapy," and again in a 1992 paper titled "Suicidal behavior and psychotropic medication," Dr. Mann laid out four study protocols which could be used by SSRI manufacturers to test the hypothesis that SSRIs pose a risk of violence and suicide for a "small vulnerable subpopulation" of patients. The tests would have either proved or disproved the causal relationship. However, Defendants chose not to conduct these prospective tests.

41. Furthermore, Defendants failed to publish any of the negative internal studies that they did regarding Lexapro and aggression, and upon information and belief, actually hid such studies from the public and government agencies.

42. In the last decade, including dates prior to April 2005, there has been a host of peer-reviewed scientific literature linking SSRIs to violence – both self-directed and other-directed. Such literature includes findings in the early 1990s from world class experts, including Teicher & Cole, Mann & Kapur, Wirshing & Van Putten, and Dr. Healy and his colleagues in the United Kingdom, warning about the rise of SSRI-induced akathisia in violence and suicide.

43. Prior to April 2005, Defendants engaged in a concerted effort to withhold negative information concerning Lexapro and misrepresented data concerning Lexapro's safety and efficacy when prescribed for depression and anxiety. Defendants suppressed the negative results of some studies which showed that Lexapro could cause an increased risk of suicidal thinking and acts in those adolescents who were prescribed it.

44. Although the Lexapro label had been approved for adults by the Food and Drug Administration (FDA) prior to February 2003, Defendants still violated FDA regulations concerning warnings. Specifically, 21 CFR § 201.57 provides that drug product "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."

45. Another regulation permits a drug company to strengthen a warning without waiting for FDA approval. Defendants failed to do this, particularly with regard to the dangers of SSRI induced violence and suicide in adolescents.

46. Prior to April 2005, there had been "reasonable evidence of an association" between serotonergic drugs and akathisia, the serotonin syndrome, and violence/suicide.

47. Prior to April 2005, drug companies like Defendants insisted that unless/until someone absolutely proved a causal relationship, they would not warn physicians or the public about the dangers of SSRIs.

48. Prior to April 2005, Defendants explicitly told their sales representative and/or agents to target child psychiatrists and pediatricians to prescribe both Lexapro and Celexa.

49. Prior to April 2005, Defendants' Speaker Bureau included child psychiatrists who would discuss the benefits of Lexapro and Celexa at various meetings.

50. In 2000, a peer reviewed article was published by Donovan and colleagues reporting on an epidemiological study, funded in part by SSRI manufacturers Eli Lilly and SmithKline Beecham. The article reports that, to a statistically significant degree, with a "p-value" of .001, the incidence of deliberate self-harm by persons on SSRI medications is 5.5 times higher than that of persons on the more traditional tricyclic antidepressants. Donovan, et al., "Deliberate Self-Harm and Antidepressant Drugs: Investigation," British J. Psych. 2000 Dec; 177 (6): 551-56, table 3.

51. In February 2000, the latest edition of the Diagnostic and Statistical Manual of Mental Disorders ("DSM-IV-TR") was published. Section 333.99 of that revision lays out the causal link between SSRIs and akathisia and thence to either violence or suicide.

52. Dr. David Healy published a paper in 2003, titled "Lines of Evidence on the Risks of Suicide with Selective Serotonin Reuptake Inhibitors," in which Dr. Healy concludes that based upon his review of randomized clinical trials (RCTs), there was a "possible doubling of the relative risk of both suicide and suicide attempts on SSRIs compared with older antidepressants or non-treatment . . ."

53. In a similar paper by Dr. Peter R. Breggin in 2003, titled "Suicidality, violence and mania caused by selective serotonin reuptake inhibitors (SSRIs): A review and analysis", Dr. Breggin concludes that "evidence from many sources confirms that [SSRIs] commonly cause or exacerbate a wide range of abnormal mental and behavioral conditions." In addition, Dr. Breggin describes such adverse drug reactions to include "mild agitation to manic psychoses, agitated depression, obsessive preoccupations that are alien or uncharacteristic of the individual and akathisia" (emphasis added).

54. On February 2, 2004, the Psychopharmacological Drugs Advisory Committee (PDAC) and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee held an advisory committee meeting, to discuss reports of the occurrence of suicidality in clinical trials for various antidepressant drugs in pediatric patients with major depressive disorder.

55. At that time in February 2004, the FDA announced a request to the manufacturers of ten antidepressant drugs, including Defendants for Lexapro, that they strengthen the "Warnings" section of the package insert to encourage close observation for worsening depression or the emergence of suicidal thinking and behavior in both adult and pediatric patients being treated with these agents, particularly for depression but also for other psychiatric and non-psychiatric disorders.

56. In March 2004, the FDA warned doctors in the United States of an increased risk of suicidality with SSRI drugs, specifically identifying Celexa and Lexapro, which are two seemingly identical drugs sold by Defendants under a license with its developer H. Lundbeck.

57. At the time of the FDA warning, H. Lundbeck revealed that it had placed a prominent suicide warning on the Celexa drug in Europe for years, although no similar

disclosure or warning had been made by Defendants in the United States for either Celexa or Lexapro.

58. H. Lundbeck also conducted a number of European trials in both hospitalized and outpatient adolescents which showed no efficacy versus placebo of Lexapro's sister drug Celexa.

59. In response to criticism that Defendants have failed to disclose such studies, in June of 2004, Defendants claimed that "the results of the European study were not hidden but were disclosed and available. In addition, the results may not be comparable . . . because of contrasting trial designs and patient populations."

60. Unfortunately, these warnings came too late to prevent Plaintiff from sustaining severe and serious personal injuries.

61. In June of 2004, the New York State Attorney General, Eliot Spitzer, requested that Defendants produce "a wide-ranging request for drug testing and drug marketing information" in particular, "about how the company tested and promoted drugs like its antidepressant Celexa for so-called off-label, or as yet-unapproved, uses."

62. Defendants continue to promote the efficacy and effectiveness of Lexapro. In a recent letter to its shareholders, Howard Solomon, Defendants' Chairman and Chief Executive Officer ("CEO"), states: "We believe that the studies and experience with our products, Lexapro and Celexa, do not indicate any increase suicidality in those age group. Even though our products are not currently approved or marketed for adolescent or pediatric use, we gladly worked with the FDA on labeling that encourages physicians and parents to observe depressed children carefully to assure that they do not act on a suicidal impulse."

63. As of date, Lexapro's own website Fact Sheet states that the most common adverse events reported in clinical trials were "nausea, insomnia, ejaculation disorder,

somnolence, increased sweating, fatigue, anorgasmia and decreased libido.” There is no mention concerning the increased risks of suicidal ideation and/or akathisia.

64. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. Defendants have kept Plaintiff ignorant of vital information essential to the pursuit of these claims without any fault or lack of diligence on Plaintiff’s part, for the purpose of obtaining delay on Plaintiff’s part in filing a complaint on his causes of action. Defendants’ fraudulent concealment did result in such delay. Plaintiff could not reasonably have discovered these claims until shortly before filing this complaint.

65. Defendants have had a continuing duty to disclose the true character, quality, and nature of the drug that Plaintiff ingested, but instead Defendants concealed it. As a result, Defendants are estopped from relying on any statute of limitations defense.

**AS AND FOR A FIRST CAUSE OF
ACTION AGAINST THE DEFENDANTS**

66. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

67. Defendants are the manufacturer of the drug known as Lexapro.

68. For years, Defendants have claimed that Lexapro does not cause suicidal tendencies in patients who are administered Lexapro.

69. Contrary to these claims, for years, Defendants were aware of clinical trials that showed that children (individuals under the age of 18) who took Lexapro suffered damaging side effects including agitation, aggression and suicidal tendencies. Additionally, these clinical trials clearly indicated that Lexapro showed no efficacy for children with major depressive disorder.

70. These clinical trial results were not matched by children given a placebo.

71. Defendants failed to inform the FDA and the public at large of the results of these clinical trials while being aware that Lexapro was being prescribed to minor patients.

72. Defendants were careless, negligent, breached its duties and obligations to Plaintiff by various sections of the Restatement of Torts (Second) including § 402(a) and are liable for causing personal injuries to Plaintiff for the following reasons:

- a) selling a product in a defective condition;
- b) selling a product which was unreasonably dangerous to the user;
- c) selling a product which was not safe for children under the age of 18 to consumer;
- d) failing to supply adequate warnings with the product;
- e) failing to provide accurate and truthful instructions to be followed with regard to the prescribing of this product;
- f) failing to warn children under the age of 18 and their parents/guardians of the dangers inherent in using this product;
- g) selling a product wherein it was foreseeable that someone would be injured upon ingesting the medication in question;
- h) selling a product which was not safe for its intended use;
- i) selling a product which was lacking of one or more elements necessary to make it safe for its intended use;
- j) manufacturing a product which was defective and which could cause injury to the user;

- k) designing a product which was defective and which could cause injury to the user;
- l) distributing a product which was defective and could cause injuries to a user;
- m) failing to see that ultimate users were advised of the dangers of said product;
- n) failing to exercise reasonable care in the design of this product;
- o) failing to exercise reasonable care in the marketing of this product;
- p) failing to adequately and properly test said product;
- q) failing to use reasonable care under the circumstances;
- r) delivering a product which was defective and could cause injury to the user;
- s) producing a product which was defective and could cause injury to the user;
- t) producing a product with component parts that Defendants knew or should have known increased the risk of harm to the user;
- u) supplying a product which was defective and could cause injury to the user; and
- v) engaging in other acts regarding the manufacturing, designing, preparing, producing, distributing, advising and selling of Lexapro as will be learned in discovery.

67. By conducting themselves as aforesaid, Defendants increased the risk of harm, thereby causing the personal injuries sustained by Plaintiff.

68. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A SECOND CAUSE OF
ACTION AGAINST THE DEFENDANTS**

69. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

70. Defendants engaged in the conduct described above and intentionally, willfully, recklessly and/or negligently caused Plaintiff severe emotional distress, prior to his attempted suicide as set forth in Restatement (Second) of Torts, § 46(1), which ultimately resulted in his attempted suicide.

71. The conduct of Defendants in making false statements to the FDA and the general public, knowing Plaintiff would rely on these statements in deciding whether to allow Plaintiff to take a medication which Defendants knew causes persons to become suicidal and which ultimately and directly resulted in Plaintiff's attempted suicide, was extreme and outrageous.

72. Plaintiff suffered severe emotional distress as a result of the conduct of Defendants.

73. Defendants' actions were willful and/or reckless thus entitling Plaintiff to punitive damages.

74. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of

this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A THIRD CAUSE OF
ACTION AGAINST THE DEFENDANTS**

75. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

76. Defendants made the following intentional misrepresentations as established by Restatement (Second) of Torts, § 402(b) and in:

- a) intentionally misrepresenting the risks and efficacy of prescribing Lexapro to persons such as Plaintiff;
- b) intentionally failing to inform Plaintiff regarding the fact that clinical trials clearly indicated that Lexapro showed no efficacy in adolescents with major depressive disorder; and
- c) intentionally failing to inform Plaintiff or physicians regarding the fact that clinical trials conducted by Defendants showed no efficacy with adolescents and showed an increased risk of akathisia and suicidality.

77. The intentional misrepresentations set forth above were done to induce Plaintiff to purchase and ingest Lexapro and to induce Plaintiff's doctors to prescribe Lexapro.

78. Such misrepresentations by Defendants concerning the increased risk of suicide associated with the consumption of Lexapro constituted an omission of a material fact.

79. The misrepresentations and omissions set forth above were done with the knowledge that the misrepresentations were false when made.

80. Plaintiff justifiably relied upon the misrepresentations and omissions set forth above in making the decision as to whether Plaintiff would ingest Lexapro.

81. As a direct and proximate result of Defendants' intentional and material misrepresentations as set forth above, Plaintiff ingested Defendants' drug which ultimately resulted in his attempted suicide.

82. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A FOURTH CAUSE OF
ACTION AGAINST THE DEFENDANTS**

83. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

84. Defendants made the following negligent and reckless misrepresentations as established by Restatement (Second) of Torts, § 525-552, in:

- a) negligently and recklessly misrepresenting the risks of prescribing Lexapro to persons such as Plaintiff;
- b) negligently and recklessly failing to inform Plaintiff regarding the fact that clinical trials clearly indicated that Lexapro showed no efficacy in adolescents with major depressive disorder; and
- c) negligently and recklessly failing to inform Plaintiff regarding the fact that clinical trials conducted by Defendants showed no efficacy with adolescents and showed an increased risk of akathisia and suicidality.

85. The negligent and reckless misrepresentations set forth above were done to induce Plaintiff to purchase Lexapro, to induce Plaintiff to ingest Lexapro and to induce his doctors to prescribe it.

86. Such negligent and reckless misrepresentations by Defendants concerning the increased risk of suicide associated with the consumption of Lexapro constituted an omission of a material fact.

87. The misrepresentations and omissions set forth above were done with the knowledge that the misrepresentations were false when made.

88. Plaintiff justifiably relied upon the misrepresentations and omissions set forth above in making the decision as to whether Plaintiff would ingest Lexapro.

89. As a direct and proximate result of Defendants' negligent and reckless material misrepresentations as set forth above, Plaintiff ingested Defendants' drug which ultimately resulted in his suicide attempt.

90. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A FIFTH CAUSE OF
ACTION AGAINST THE DEFENDANTS**

91. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

92. Defendants expressly represented to the users and their physicians that Lexapro was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did

not produce any side-effects dangerous to life, and that it was adequately tested and fit for its intended use.

93. Members of the medical community in general, and Plaintiff's treating physicians in particular, relied upon the representations and warranties of Defendants for use and ingestion of Lexapro in prescribing, recommending and /or dispensing Lexapro.

94. Defendants knew or should have known that said representations and warranties were false, misleading and untrue in that Lexapro was not safe and fit for the use intended, and, in fact, produces serious injuries and/or death to the user. As a result of the aforementioned breach of warranties Plaintiff was caused to attempt to commit suicide.

95. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A SIXTH CAUSE OF
ACTION AGAINST THE DEFENDANTS**

96. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

97. Defendants impliedly represented to the users and their physicians that Lexapro was safe and fit for use for the purposes intended, that it was of merchantable quality, and that it did not produce any side-effects dangerous to life, and that it was adequately tested and fit for its intended use.

98. Members of the medical community, and Plaintiff's treating physicians in particular, relied upon the representations and warranties of Defendants for use and ingestion of Lexapro in prescribing, recommending and /or dispensing Lexapro.

99. Defendants knew or should have known that said representations and warranties were false, misleading and untrue in that Lexapro was not safe and fit for the use intended, and, in fact, produces serious injuries and/or death to the user.

100. As a result of the aforementioned breach of warranties by Defendants, Plaintiff was caused to attempt to commit suicide.

101. By reason of Defendants' actions as aforementioned, Defendants are liable to the Plaintiff.

102. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A SEVENTH CAUSE OF
ACTION AGAINST THE DEFENDANTS**

103. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

104. At all times hereinafter mentioned, Defendants were under a duty to exercise reasonable care in the design and development of Lexapro and, in particular, in the advertising, marketing and promoting Lexapro, both directly and indirectly, to ensure that Lexapro was not used in the treatment of nervousness for which it was not effective and to ensure that Lexapro

was not used in a manner or to treat conditions where Defendants knew or should have known that the user could sustain injuries and harm from the drug.

105. Defendants negligently, recklessly, grossly negligently wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that Defendants directly and indirectly, advertised, marketed and promoted Lexapro for the treatment of nervousness, even though Lexapro had not been scientifically determined to be safe for the treatment of such condition, and even though Lexapro was, in fact, not reasonably safe for the treatment of such condition. Furthermore, Defendants failed to adequately warn of the risk of suicide or aggressive, self-destructive behavior of which Defendants knew or should have known about.

106. Defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others not only by manufacturing, distributing, selling, advertising, marketing and promoting Lexapro even though such drug was not safe or effective because it caused or influenced minors using the drug for any purpose to engage in self-destructive behavior including committing suicide, but also by failing to adequately warn the public of such risks.

107. The aforesaid incident and the injuries sustained by Plaintiff were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including Plaintiff on the part of Defendants in the design, manufacture, distribution, advertising, marketing and promoting of Lexapro as being safe and effective in the treatment of nervousness and by inducing the public, including Plaintiff, to believe that Lexapro was effective in the treatment of nervousness.

108. At all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of personal injuries sustained by Plaintiff.

109. At all times hereinafter mentioned, Plaintiff did not contribute to his injuries by reason of any negligence or culpable conduct on his part.

110. By reason of the foregoing, Plaintiff was caused to sustain severe and serious personal injuries to his mind and body.

111. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR AN EIGHTH CAUSE OF
ACTION AGAINST THE DEFENDANTS**

112. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

113. State and federal laws and regulations alleged to be violated herein, specifically those regulating the efficacy and distribution of drugs to adolescents and adults, in effect at the time such harm occurred to Plaintiff dictated the standard of care imposed upon Defendants.

114. Defendants' negligent and reckless violation of said laws and regulations deems that Defendants were negligent as a matter of law.

115. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of

this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A NINTH CAUSE OF
ACTION AGAINST THE DEFENDANTS**

116. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

117. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of Plaintiff.

118. Defendants' intentional, wanton, willful and outrageous actions consisted of, but are not limited to:

- a) intentionally failing to conform to FDA guidelines;
- b) intentionally failing to disclose clinical trial data which indicated that Lexapro showed no efficacy in the adolescent population;
- c) intentionally failing to disclosed clinical trial data which indicated that Lexapro increased the rate of akathisia in the adolescent population;
- d) intentionally failing to disclosed clinical trial data which indicated that Lexapro increased the risk of suicide and suicidal ideation in the adolescent population; and
- e) intentionally and recklessly failing to report to the FDA that patients, prior to Plaintiff, suffered significant liver toxicity which required that the study be put on hold.

119. By reason of the wanton, willful and outrageous conduct of Defendants , as aforesaid, Plaintiff was caused to sustain the catastrophic injuries which ultimately resulted in his attempted suicide as described above.

120. By reason of the wanton, willful and outrageous conduct of Defendants, pursuant to the Restatement of Torts, § 908(1), Defendants are liable for punitive damages and relief as this Court deems just.

121. By reason of the facts and premises aforesaid, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

(1) The sum of \$100,000,000.00 on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(2) The sum of \$100,000,000.00 on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(3) The sum of \$100,000,000.00 on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(4) The sum of \$100,000,000.00 on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(5) The sum of \$100,000,000.00 on the Fifth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(6) The sum of \$100,000,000.00 on the Sixth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(7) The sum of \$100,000,000.00 on the Seventh Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(8) The sum of \$100,000,000.00 on the Eighth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; and

(9) The sum of \$100,000,000.00 on the Ninth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action, together with the interest, costs and disbursements of this Action.

Dated: January 3, 2008

FINKELSTEIN & PARTNERS, LLP
Attorneys for Plaintiff
436 Robinson Avenue
Newburgh, NY 12550
(866) 909-8678

BY: 

ANDREW G. FINKELSTEIN, ESQ.
(AF 1070)

TO: FOREST LABORATORIES, INC.

Defendant

909 Third Avenue

New York, NY 10022

FOREST PHARMACEUTICALS, INC.

Defendant

909 Third Avenue

New York, NY 10022